

In the Matter of:

FDA DOCKET: 00N-1571

RMO 13

previously been placed onto this Docket, some of them by the same party now moving to file them again.¹

Given the fact that this submission comes only one week prior to the deadline for submission of CVM's written direct testimony, and the fact that it is virtually impossible for CVM to review and respond to these new documents in its written direct testimony, CVM requests that the Administrative Law Judge order Bayer to provide CVM and the record with an index of the documents and to withdraw documents from this Motion that are already elsewhere on Docket 00N-1571 before CVM is required to respond to Bayer's Motion; but not before December 10.

Further, given the number of documents involved, CVM requests that once Bayer has indexed and consolidated its submission, CVM be given an additional 10 days to review the documents before responding to this Motion.

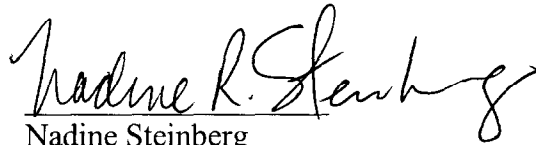
Finally, for those documents ordered to be placed on Docket No. 00N-1571, CVM requests that any such Order include the opportunity for CVM to submit additional testimony, if necessary, to address factual information and/or expert opinion contained in these documents, and a reasonable time period in which to prepare such additional direct testimony.²

CVM wants to clarify that it is not, at this time, objecting to the documents. In fact, an initial cursory review indicates that many of these documents are non-objectionable. CVM is merely asking that, in light of this eleventh-hour submission, CVM be granted the time to

¹ For example, an initial review by CVM counsel revealed that the following documents subject to this Motion, labeled B-1531, B-1546, B-1555, B-1776, B-1777, B-1780, B-1783, B-1787, B-1788, and B-1803 already appear on Docket 00N-1571 as G-1715, G-258, G-1772, B-609, B-122, B-186, B-287 (and G-169), B-413 (and G-299), B-423 (and G-307), and, G-586, respectively. CVM has not had a chance to conduct a systematic review of materials subject to this motion to see whether other documents are on the current Docket.

review an indexed and consolidated submission prior to having to respond to Bayer's Motion to Supplement, and for CVM to be able to present additional direct testimony on any such "new" document that is added to the Docket at this late date.

Respectfully submitted,

A handwritten signature in black ink, reading "Nadine R. Steinberg". The signature is fluid and cursive, with a long horizontal stroke at the end.

Nadine Steinberg
Counsel for CVM
5600 Fishers Lane (GCF-1)
Rockville, MD 20850
(301) 827-5050

²If the Administrative Law Judge denies Bayer's Motion to Supplement its Document Submission, CVM respectfully requests that the Order specify that those documents, not elsewhere on the record, will not be available to any party or participant to cite in its written direct testimony or other pleadings, including its post-hearing briefs.

CERTIFICATE OF SERVICE

I hereby certify that an original and a copy of the foregoing Center for Veterinary Medicine's Response to Bayer's Motion to Supplement its Document was hand delivered this 6th day of December, 2002, to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

I also certify that a copy of CVM's Response has been hand delivered, this 6th day of December, 2002, to:

The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy of CVM's Response was e-mailed and also mailed, postage prepaid, this 6th day of December, 2002, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

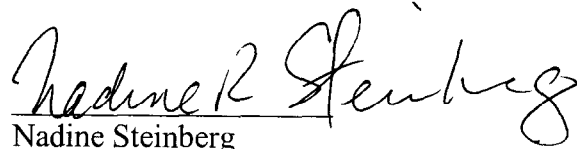
and

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

I also certify that a copy of CVM's Response was e-mailed, this 6th day of December, 2002, to:

Judge Daniel Davidson
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

Dated: 12/6/02

A handwritten signature in cursive script, reading "Nadine R Steinberg". The signature is written in dark ink and is positioned above the printed name.

Nadine Steinberg
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